Response to Public Comments

The draft Part 70 Operating Permit for Mallinckrodt, LLC was placed on public notice May 12, 2017 for a 30-day comment period. The public notice was published on the Department of Natural Resources' Air Pollution Control Program's web page at: http://www.dnr.mo.gov/env/apcp/PermitPublicNotices.htm. Public comments were received from Mr. Mark Smith, EPA Region 7, citizens of St. Louis, and Mr. Bob Menees, Great Rivers Environmental Law Center. The comments are addressed in the order in which they appear within the letter(s).

Comments received from Mr. Mark Smith, EPA Region 7: Mr. Smith, Comment #1:

First, Permit Condition Plant Wide VE20 incorporates applicable requirements from 10 CSR 10-6.220-Restriction of Emissions of Visible Air Contaminants and from Permit to Construct 03-01-002PM. Permit Condition Plant Wide VE20 requires the permittee to "not cause or permit to be discharged into the atmosphere from any emission unit any visible emission greater than 20% for any continuous six minute period." Permit Condition Plant Wide VE20 also requires the permittee to conduct "visible emission observations on each emission unit using procedures contained in USEPA Test Method 22, weekly for a minimum of eight (8) weeks after permit issuance." USEPA Test Method 22 requires the use of an observation period of sufficient length to meet the requirements for determining compliance with the emission standard. Therefore, to meet the requirements of Permit Condition Plant Wide VE20, each emission unit shall be observed for six minutes each week for a minimum of eight weeks. Additionally, USEPA Test Method 22 requires observer rest breaks of not less than 5 minutes and not more than 10 minutes after every 15 to 20 minutes of observation. In other words, for every hour of observation, 15-20 minutes of rest is required, allowing a single observer time to evaluate 6 – 7 emissions units.

According to the Application for Authority to Operate, submitted by Mallinckrodt, LLC dated May 10, 2017, approximately five hundred and sixty-five (565) emission units are subject to this operating permit Plant Wide permit condition. Conducting 565 six-minute visible emission observations will require approximately ninety-four hours of observation every week for a minimum of eight weeks.

We recognize that 10 CSR 10-6.220 may apply to each of the 565 emissions units, but it's not clear from the Title V permit or Statement of Basis if all of these points can be reasonably expected to have visible emissions. For example, emission points exclusively emitting VOC or HAPs, or those combusting natural gas, may be unlikely to have any visible emissions. If so, MDNR could provide rationale in the Statement of Basis why a visible emissions assessment is not necessary for select emission points and may be able to significantly reduce the number of Method 22 observations that need to be made. We recommend that MDNR and Mallinckrodt re-evaluate which emission points may have visible emissions and prioritize Method 22 observations for those units.

Response to Mr. Smith, Comment #1:

The permit condition has been changed to indicate Method 22 like procedures be used as a qualitative screening for the presence of visible emissions. The Method 22 like procedures are not intended to directly determine compliance with the emission standard, as the method cannot be used to quantify

opacity. Only if visible emissions are observed would a Method 9 observation be required. While there may be some emission units that may be unlikely to emit visible emissions, almost every issued construction permit applies a 20% opacity limitation on a plant wide basis. Only one is cited in the permit condition as to cite all of them is redundant. To remove this requirement, and update the applicability with our current standards, would require the amendment of almost every active construction permit. At this time, the permittee has agreed to continue the Method 22 like and any subsequent Method 9 observations as required in this operating permit. The permittee understands the procedures and expenses required to amend the underlying construction permits and may obtain future amendments as allowed by 10 CSR 10-6.060, *Construction Permits Required*.

Mr. Smith, Comment #2:

Second, Permit Condition GGG, beginning on page 13 of the draft operating permit on public notice, incorporates the applicable requirements from 40 CFR part 63, Subpart GGG-National Emission Standards for Pharmaceuticals Production. Permit Condition GGG indicates that these requirements apply to Buildings 6, 7, 223, 235, 250, 260, 504, 505, 507, 512, 514, 516, Plant 5 T-530 and Plant 1 T-0015. Within these fourteen (14) areas, there are over five hundred (500) unique individual emission units. 40 CFR part 63, Subpart GGG defines the affected source as the pharmaceutical manufacturing operations that manufacture a pharmaceutical product; are located at a plant site that is a major source; and process, use or produce HAP. 40 CFR part 63, Subpart GGG goes on to define process as all equipment which collectively function to produce a pharmaceutical product or isolated intermediate. It is likely that Mallinckrodt, LLC has more than one (1) process (as defined) within these fourteen (14) identified buildings; using these over five hundred (500) unique emission units. Additionally, it is unclear to EPA, which of the forty-five (45) pages of requirements in Permit Condition GGG apply to each of the emission units.

EPA's White Paper #2 for Improved Implementation of the Part 70 Operating Permits Program says that Section 504 (a), of the Clean Air Act, states that each permit shall include enforceable limitations and standards and such other conditions as necessary to assure compliance with the applicable requirements. In addition, Section 504 (c) requires each permit to set forth inspection, entry, monitoring, compliance certification and reporting requirements to assure compliance with the permit terms and conditions. EPA interprets this to mean that the operating permit shall ensure that all applicable emission limits are placed in the Part 70 permit and attached to the emission unit(s) to which they apply. This approach provides for enforceability from a practical standpoint. One of the goals of the Title V (Part 70) operating permit program is that both the source (Mallinckrodt, LLC) and permitting authority (MDNR) gain a better understanding of the specific requirements applicable to the source, which in turn will lead to improved compliance. There is value to be gained by a source and the permit writer by studying the specific requirements of specific standards, parsing out these requirements that apply to the source and translating them in a logical fashion as operating permit conditions. Through this exercise, the source, the permitting authority and the public gain a better understanding of the requirements in general as well as how the standards specifically affect the source. Therefore, EPA recommends MDNR and Mallinckrodt re-visit their approach in presenting how the applicable emission limits, standards, compliance procedures, monitoring, record keeping and reporting specified by 40 CFR part 63, Subpart GGG are attached to approximately 500 emission units included within Buildings 6, 7, 223, 235, 250, 260, 504, 505, 507, 512, 514, 516, Plant 5 T-530 and Plant 1 T-0015. For example, a building by building approach to organizing emission units and associated applicable requirements may assist an

inspector, the company and the public to assess compliance with the pharmaceutical MACT requirements. Even though potentially duplicative, this approach would minimize any confusion over what parts of the rule apply to individual emissions and or process units.

Response to Mr. Smith, Comment #2:

Clarifying language has been added to page 6, in the description of Emission Units with Limitations to explain how the specific emission units and applicable permit conditions are correlated. Attachment A correlates applicable regulations with emission units on a building by building basis. Additionally, footnotes have been added to all Permit Conditions to direct the reader to Attachment A as well as any other pertinent attachments or appendices.

Mr. Smith, Comment #3:

Third, the operational limitation in Permit Condition 092014-001 for Building 97, as listed in Section IV: Emission Unit Specific Emission Limitations, requires the permittee to exclusively use EP-2913 Conical Dryer to produce the pharmaceuticals in the following table. The draft permit states that the contents of the table are confidential business information and no table is included in Permit Condition 092014-001. Section 503(c), of the Clean Air Act, provides that certain information generated pursuant to a State's operating permit program must be made available to the public. This includes any permit, permit application, monitoring report and certification created during the implementation of the program. Section 503 (e) further establishes that the contents of a Title V (Part 70) operating permit shall not be entitled to protection under section 114 (c). Therefore, EPA recommends MDNR and Mallinckrodt, LLC reconsider the assertion that the information in the table in Permit Condition 092014-001 is confidential business information, or otherwise explain in the Statement of Basis why the information is being withheld.

Response to Mr. Smith, Comment #3:

The project and review that resulted in issuance of Construction Permit 092014-001 contained confidential business information for which the installation requested confidential treatment under 10 CSR 10-6.210, *Confidential Information*. Missouri law provides that the Department shall not disclose confidential information. *See* Sections 643.050.5 and 643.151.4, RSMo. The Department reviewed the request for confidential treatment under 10 CSR 10-6.210 and determined that such treatment is warranted

Mr. Smith, Comment #4:

Fourth, Permit Condition 99-11-078; Permit Condition 022016-012; and Permit Condition 072014-004 all incorporate applicable requirements from construction permits for multiple emission units associated with Building 260. Each of these three (3) permit conditions requires the permittee to either comply with emission limitations; keep records and / or conduct monitoring as required in 40 CFR part 63, Subpart GGG. This draft operating permit includes a "Multi-Building Emission Limitation" in Section III, which most likely captures the requirements in Permit Condition 99-11-078; Permit Condition 022016-012; and Permit Condition 072014-004. EPA believes this offers an opportunity for MDNR and Mallinckrodt, LLC to undertake a "permit streamlining" effort. As previously discussed in the second comment above, EPA's expectation is that all applicable emission limits will be attached to specific emission units to ensure enforceability as a practical matter. Therefore, EPA recommends MDNR

include specific limitations in Permit Condition 022016-012 or its equivalent for Building 260 under Permit Condition GGG.

Response to Mr. Smith, Comment #4:

The pertinent language for Permit Condition 99-11-078; Permit Condition 022016-012; and Permit Condition 072014-004 has been changed from referencing 40 CFR part 63 Subpart GGG, to referencing Permit Condition GGG.

Mr. Smith, Comment #5:

Fifth, Permit Condition Dc; Permit Condition Subpart DDDDD; Permit Condition 5.510-Conditional Exemption; and Permit Condition 11-04-008 in Section IV: Emission Unit Specific Emission Limitations, all pertain to boilers and / or boilers and cooling tower. EPA believes it would be beneficial if these permit conditions either included the pertinent boiler and cooling tower information or referenced the boiler and cooling tower information contained in Attachment A. Additionally, Permit Condition 5.510-Conditional Exemption and Permit Condition 11-04-008 both require the permittee to use Attachment K, or equivalent, to demonstrate compliance. Attachment K includes a nitrogen oxides (NOx) emission factor, the source of which is not referenced. EPA recommends MDNR and Mallinckrodt, LLC include an emission factor reference to improve the enforceability of Attachment K. Also, Monitoring / Record keeping requirement 4), in Permit Condition 11-04-008 requires the permittee to maintain records of any water treatment chemical added to the cooling tower. MDNR's customary practice is to provide examples of compliance verification data collection records as attachments to operating permits for public review and comment. However, the water treatment chemical addition record, reference in this permit condition has not been attached and EPA suggests MDNR follow their customary practice and attach the data sheet to this operating permit.

Response to Mr. Smith, Comment #5:

Attachment K references the source of the nitrogen oxides (NOx) emission factor as the construction permit and manufacturer's specifications. Manufacturer's specifications present the value in units of ppmv. The construction permit contains the calculations to convert the value into units of pounds per million cubic feet. These calculations have been added to the attachment.

Permit Condition 11-04-008 contains an Operational Limitation prohibiting the usage of chromium containing water treatment chemicals in the cooling tower, with a Monitoring/Recordkeeping requirement to maintain records of any water treatment chemicals added to the tower. The intent is for the installation to maintain safety data sheets (SDS) or similar documentation. SDS retention has been added to Plant Wide Emission Limitations, Recordkeeping #4 to ensure compliance.

Mr. Smith, Comment #6:

Sixth, Permit Condition ZZZZZ-Conditional Exemption; Permit Condition Subpart ZZZZ-New and Limited; Permit Condition Subpart ZZZZ-Existing Emergency; and Permit Condition Subpart ZZZZ-New CI Emergency all reference applicable requirements associated with Mallinckrodt's thirteen (13) emergency engines. However, none of these four (4) permit conditions readily identify to which emergency engine(s) the requirements are applicable. EPA believes it would be beneficial if each permit condition included pertinent emergency engine information or each permit condition referenced the appropriate information in Attachment A.

Response to Mr. Smith, Comment #6:

Clarifying language has been added to page 6, in the description of Emission Units with Limitations to explain how the specific emission units and applicable permit conditions are correlated. Attachment A is a building by building approach which organizes emission units and applicable regulations. Additionally, footnotes have been added to all Permit Conditions to direct the reader to Attachment A as well as any pertinent attachments or appendices.

Mr. Smith, Comment #7:

Finally, Permit Condition 6.261 incorporates applicable requirements from 10 CSR 10-6.261 as it applies to emergency engines associated with the generators in Building Z, 62, 97, 250, 260 and 505. 10 CSR 10-6.261 is a State of Missouri regulation which has not yet been adopted into the EPA approved Missouri State Implementation Plan (SIP), and therefore, this is a "State Only" requirement and Permit Condition 6.261 should be identified as "State Only."

Response to Mr. Smith, Comment #7:

A note has been added to Permit Condition 6.261 to indicate the regulation is a state only requirement unless it is incorporated in the Missouri SIP as a final EPA action.

Comments received from Comment #1:

There needs to be greater communication from DNR to the surrounding communities around pollution-emitting sources, air permit renewals and new permits. This should take the form of public announcements in local periodicals like The St. Louis American and on the DNR web site specifically designed for the citizens of Missouri by location. Additionally, there should be a grievance form created to capture the salient information for DNR to take action.

Response to Comment #1:

Air permit public notices are provided at the following website: http://dnr.mo.gov/env/apcp/permit-public-notices.htm in accordance with 10 CSR 10-6.065(7). The public notice website provides a sign up link to receive e-mail notifications when updated information is published on the website. For permits that are under review, but not yet issued, information may be obtained at the following website: http://dnr.mo.gov/env/apcp/pending-projects-search.php. This website allows searching of active projects on a county and city level. Issued permits are available at the following website: http://dnr.mo.gov/env/apcp/completed-projects-search.php, which also allows searching on a county and city level.

The Department provides the public the ability to submit environmental concerns through an online form that can be found at: https://dnr.mo.gov/concern.htm.

, Comment #2:

A designated staff role within DNR should be given as a community liaison and publicized as such.

Response to Comment #2:

The public is encouraged to contact the Air Pollution Control Program or the Department's Regional Offices to discuss any concerns. Contact information for the main and regional offices is located at the following website: http://dnr.mo.gov/regions/index.html.

, Comment #3:

There needs to be a cumulative impact analysis on the effects of Mallinckrodt and other air polluters on the health of environmental justice neighborhoods in North St. Louis City. In particular, effects and presence of PM2.5, PM10, VOCs and NOx.

Response to Comment #3:

The Title V permitting scheme does not require a "cumulative impact analysis." The Department monitors air quality throughout the state. Monitoring information is available at the following website: http://dnr.mo.gov/env/apcp/airpollutants.htm .

, Comment #4:

Response to Comment #4:

The Department acknowledges and recognizes that good communication between businesses and their surrounding communities is beneficial and encourages the commenter and the permittee to communicate. The Department must focus its resources on the Department's mission-critical work.

Comments received from Mr. Bob Menees, Great Rivers Environmental Law Center:

Mr. Menees' comments have been summarized into the three categories below. His entire comment letter appears as Response to Comments-Attachment 1 at the end of this Response to Comments document.

- 1. Compliance with Title VI, EPA Regulations, and Executive Order 12898
- 2. Emission Limitations
- 3. General typographical errors

1. Mr. Menees, Category 1 Comments: Compliance with Title VI, EPA Regulations, and Executive Order 12898

To remedy violations of Title VI, EPA regulations, and Executive Order 12898, MDNR should require Mallinckrodt to conduct a robust analysis of disproportionate impacts to North St. Louis City communities, including cumulative impacts from other nearby permitted facilities regulated by MDNR under the CAA, and allow public comment on that disproportionate impacts analysis. Alternatively, MDNR should conduct such analysis itself for public comment. MDNR should develop a complaint procedure whereby members of minority and low-income communities are provided a vehicle to address potential environmental justice and civil rights issues in MDNR's air permitting process.

Response to Mr. Menees, Comment Category #1, regarding compliance with Title VI, EPA regulations, and Executive Order 12898

Neither the Department nor Mallinckrodt are required to conduct the analysis Mr. Menees requests. If an application complies with the requirements of the State's authorized permit program, and the source is in compliance with its construction permit(s), the Department must issue the permit in accordance with § 643.078, RSMo. The Department notes, however, that the state and federal regulations the Department applies in developing and issuing Title V Part 70 operating permits were promulgated to protect human health and the environment from potential adverse impacts of air pollution.

The Department complied with Title VI of the Civil Rights Act of 1964 in developing this permit.

Opportunities to express concerns are available. The Department maintains the following website to solicit public participation: http://dnr.mo.gov/env/apcp/permit-public-notices.htm. The public can sign up to receive e-mail notices when a new permit is posted for public comment by following the instructions on the form that appears after clicking on the graphic that reads, "Get Updates on this Issue." This website contains information on permits that are open for public comment and other air quality issues for which the Department is soliciting public comments. Also, the public is encouraged to contact the Air Pollution Control Program or our Regional Offices to discuss any concerns. Contact information for the main and regional offices is located at the following website: http://dnr.mo.gov/regions/regions.htm.

2. Mr. Menees Category 2 Comments: Emission Limitations

Mr. Menees states several emission limits presented in Section III of the draft permit should be lowered because they will not be protective of ambient air quality and human health. His comments are addressed below.

Response to common comments that emission limits should be lowered:

The Purpose of the Part 70 Operating Permit program is not to revise or reevaluate construction permit emission limitations. It is the purpose of a Part 70 Operating Permit to serve as a single document which contains all applicable regulations at the time of permit issuance. The Title V program does not impose new substantive air quality control requirements. It does contain requirements sufficient to demonstrate compliance with applicable regulations which enables the states, EPA, and public to understand better the requirements to which the source is subject and whether the source is meeting those requirements.

Emission Inventory Questionnaires (EIQs) are used by installations to report their actual emissions on a calendar year basis. Permits are based on potential emissions, which represent the worst case emissions for year round operation. Often, installations do not operate all processes year round so the actual emissions are much less than the potential emissions. It is important to note that emission limitations imposed by a construction permit issued pursuant to 10 CSR 10-6.060 are for a consecutive 12 month period, not a calendar year.

Additionally, if the permittee undergoes any physical change in or change in the method of operation, then a construction permit evaluation must be conducted under the provisions of 10 CSR 10-6.060, Construction Permits Required. Also, if any new applicable regulations are promulgated during the term of the Operating Permit, the installation must demonstrate compliance with the new regulations. Ambient air monitoring and compliance with the NAAQS may be included in the permit review as provided in 10 CSR 10-6.060.

Mr. Menees, Comment Category #2, Comment #1: Regarding NOx emissions

The limit in the draft permit for NOx is 39 tons per year (tpy) for all permitted features. Mallinckrodt's Emission Inventory Questionnaires ("EIQs") from 2008-2016 demonstrate a downward trend of NOx emissions from 107.1 tpy in 2008 to 29.30 tpy in 2016. Allowing Mallinckrodt to suddenly reverse trend and emit 10 tpy more in 2017 than in 2016 would constitute a significant increase of NOx into the ambient air in an area that is already designated as non-attainment for ozone and PM_{2.5}. Since NOx is a precursor for ozone, allowing Mallinckrodt to emit 10 tpy will further contribute to ambient air quality exceedances and violations of the ozone NAAQS. Furthermore, NOx is a precursor to PM2.5. As stated above, the area around the facility is already in non-attainment for PM2.5 and experiences the highest levels of PM_{2.5} in the ambient air statewide. Allowing an additional 10 tpy of NOx per year will further degrade the ambient air in North St. Louis City. A review of a prior draft permit from 2013 suggests that 24.45 tpy would be an appropriate limit in Mallinckrodt's permit and that the 39 tpy limit in the draft permit was arbitrarily selected without justification for the convenience of the permittee. Selecting the 24.45 tpy emission limit for NOx would continue the downward trend and would help to meet ozone and PM_{2.5} NAAQS in the region and help to improve ambient air quality in North St. Louis City.

Response to Mr. Menees, Comment Category #2, Comment #1: Regarding NOx emissions
The draft permit contains two permit conditions which apply NOx limitations to equipment. Permit
Condition 01-09-027PM establishes a less than 39 tpy NOx emission limitation to the units
contained in construction permit 01-09-027 and subsequent amendments. Permit Condition 11-04008 establishes a less than 40 tpy NOx limitation on the boilers contained in construction permit 1104-008. These permits were issued under the procedures found in 10 CSR 10-6.060, Construction
Permits Required, specifically Section (5), De Minimis Permits. To obtain a Section (5) permit, the
project must have a net emissions increase below the de minimis levels. For NOx, the de minimis
level is 40 tpy.

The initial construction permit 01-09-027, issued July 18, 2002 contained a NOx limitation of 24.25 tons on the new thermal oxidizer system. This limitation was imposed upon the installation to reflect the perceived potential to emit of the equipment contained in the permit. In 2006, the installation discovered that potential NOx emissions from the thermal oxidizer were higher than reflected in the permit. In accordance with 10 CSR 10-6.060, the installation submitted an amendment request to reflect the higher potential emissions. Since the potential emissions were above the de minimis level of 40 tons, the installation accepted a limitation to less than de minimis levels to maintain compliance.

The Missouri Air Pollution Control Program has submitted three years of PM2.5 monitoring data demonstrating compliance with both the 1997 and 2006 PM2.5 NAAQS for the St. Louis area. Upon EPA approval the area will be re-designated an attainment maintenance area for 1997 PM2.5 NAAQS and an attainment area for the 2006 PM2.5 NAAQS. The program provides air monitors for various pollutants throughout the state. Monitoring information is available at the following website: http://dnr.mo.gov/env/apcp/airpollutants.htm

Mr. Menees, Comment Category #2, Comment #1: Regarding VOC emissions

The Total VOC emission limit of 211.82 tpy is more than five times higher than Mallinckrodt's VOC emissions reported in its 2016 EIQ of 38.10 tpy. The most VOCs Mallinckrodt has emitted since 2008 is 43.8 tpy. Setting the emission limit at 211.82 tpy would allow Mallinckrodt to emit VOCs in a quantity that would negatively impact human health and ambient air quality. Furthermore, because VOC is a precursor to ozone, allowing a five-fold increase in VOC emissions from one source would likely contribute to further exceedances of the ozone NAAQS in an area of non-attainment for ozone.

Response to Mr. Menees, Comment Category #2, Comment #2: Regarding VOC emissions
Permit Condition 01-09-027PM establishes a 211.82 ton VOC emission limitation to the units
contained in construction permit 01-09-027 and subsequent amendments. This value appears in the
initial construction permit 01-09-027, issued July 18, 2002 for installation of a thermal oxidizer
system. This permit superseded eleven previously issued construction permits/source registrations,
and consolidated those operations into this single permit. The VOC limitations from those
superseded permits were brought forward into this permit, with a total value of 204.83 tons. The
potential VOC emissions from the new thermal oxidizer system were 6.99 tons which yields a total
VOC potential of 211.82 tons.

Mr. Menees, Comment Category #2, Comment #3: Regarding HAPs emissions

The Total HAP limit of 143.43 tpy is significantly higher than Mallinckrodt's reported HAPs from 2012-2016, which ranged from 1.18 tpy to 3.12 tpy. It is unclear from the Statement of Basis or other documents in Great Rivers' possession why there is such a vast discrepancy between reported HAPs and proposed HAP emission limits. We note that in earlier years, Mallinckrodt and/or MDNR were combining VOC and PM10 with HAPs in EIQs. However, these values still do not explain the vast discrepancy described above.

MDNR's allowance of 143.43 tpy or 286,860 lbs per year for the next five years to Mallinckrodt to emit air pollutants deemed hazardous for being suspected of causing cancer or other serious health effects, such as reproductive effects or birth defects, will have a disproportionate impact on minority and low-income communities near the facility.

Response to Mr. Menees, Comment Category #2, Comment #3: Regarding HAPs emissions Permit Condition 01-09-027PM establishes a 143.43 ton total HAP emission limitation to the units contained in construction permit 01-09-027 and subsequent amendments. This value appears in the initial construction permit 01-09-027, issued July 18, 2002, for installation of a thermal oxidizer system. This permit superseded eleven previously issued construction permits/source registrations, and consolidated those operations into this single permit. The HAP limitations from those

superseded permits were brought forward into this permit, with a total value of 136.93 tons. The potential HAP emissions from the new thermal oxidizer system were 6.50 tons which yields a total HAP potential of 143.43 tons.

3. Mr. Menees, Comment Category #3: General typographical errors

Mr. Menees provides non-substantive suggested corrections to the draft permit for accuracy. See Response to Comment, Attachment 1 for the detailed comments.

Response to Mr. Menees, Comment Category #3, Comment #1: All corrections except one have been incorporated into the permit as suggested. The wording on Page 62 was changed in response to a comment received from being applicable.

Comment received from Comment #1:

I am humbly writing to inform you of my concerns regarding the possible pollution hazard in our neighborhood. I live from Mallinckrodt Pharma. My concern is the well-being of the school children of Clay Elementary SLPS, and Holy Trinity Catholic School, and the community which lives here. I am planning a museum development at the 'old' Divoll Library located right next door to Clay School. It will become a Museum of the Arts and Sciences for Children K-12 and beyond. We will present Mythological stories and lessons, which the take-away is, 'Philosophy - as a way of life.' We all must set virtuous examples by practice. Philotimo!

Response to [1] (6) Privately, (6) (7) (6) Personne, Comment #1:

It is the purpose of a Title V (Part 70) Operating Permit to serve as a single document which contains all applicable regulations at the time of permit issuance. The Title V program does not impose new substantive air quality control requirements. It does contain requirements sufficient to demonstrate compliance with applicable regulations; which enables the states, EPA, and public to understand better the requirements to which the source is subject and whether the source is meeting those requirements.

If Mallinckrodt undergoes any physical change in or change in the method of operation, then a construction permit evaluation must be conducted under the provisions of 10 CSR 10-6.060, Construction Permits Required. Ambient air monitoring and compliance with the NAAQS may be included in the permit review as provided in 10 CSR 10-6.060. Also, if any new applicable regulations are promulgated during the term of the Operating Permit, the installation must demonstrate compliance with the new regulations.

Response to Comment Attachment 1



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June 12, 2017

VIA ELECTRONIC MAIL ONLY

Chief, Permits Section
Missouri Department of Natural Resources
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P.O. Box 176
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Re: Mallinckrodt, LLC Draft Part 70 Operating Permit, (Installation ID: 510-0017; Project No. 1997-05-009)

Dear Sir or Madam:

On behalf of the Missouri State Conference of the (b) (6) Privacy, (b) (7)(C) Personal Privacy, and other concerned citizens of the (b) (6) Privacy, (b) (7)(C) Personal Privacy, and other concerned citizens of the (b) (6) Privacy, (b) (7)(C) Personal Privacy neighborhoods in North St. Louis City, Great Rivers Environmental Law Center ("Great Rivers") submits the following comments regarding Mallinekrodt, LLC's ("Mallinekrodt") Draft Part 70 Operating Permit issued by the Missouri Department of Natural Resources ("MDNR").

I. Introduction

The mission of the properties of the political of the mission of the persons and to eliminate race-based discrimination. Furthermore, the properties of all persons and to eliminate race-based discrimination. Furthermore, the properties of the persons and to eliminate race-based discrimination. Furthermore, the properties of the proper

Great Rivers Environmental Law Center June 12, 2017 Page 2 of 9

efficiency and clean energy, strengthen community resiliency and livability. Similarly, Great Rivers has dedicated much time and effort since 2012 to investigate and attempt to alleviate the negative impacts imposed on North St. Louis City residents and workers from the pollution caused by businesses located in and near the North St. Louis Riverfront Corridor. Immediately prior to the start of Great Rivers' work on this issue, the City of St. Louis Department of Health lost funding to operate most of its air pollution program under its Certificate of Authority issued by the Missouri Air Conservation Commission ("MACC").

Since then, MDNR has since been the primary enforcer of the mandates of the federal Clean Air Act ("CAA") and Missouri Air Conservation Law ("MACL") in the City of St. Louis. While we appreciate the difficulties that have been created by this transition and the efforts taken by MDNR to address air quality issues in the City of St. Louis, we believe that more needs to be done to address environmental justice issues faced by minority and low-income communities in North St. Louis that are caused by this dense corridor of pollution.

The communities most impacted by the decision to issue Mallinckrodt a Clean Air Act. Title V, Part 70 Operating Permit are the (b) (6) Privacy, (b) (7)(C) Personal Privacy neighborhoods in North St. Louis City, which are located within zip codes (composition of these three neighborhoods is primarily minority and low-income and therefore they constitute Environmental Justice communities under EPA Title VI Civil Rights regulations and policy. According to a 2012 St. Louis City Department of Health report entitled Understanding Our Needs, the city's populations located within zip codes (have the highest poverty rate in the city (46.3% and 34.4% respectively). The same report indicates that populations located within zip codes (and 34.4% respectively). The same report indicates that populations located within zip codes (codes (code)) (code) (code)

MDNR's permitting program in this area of North St. Louis causes a disparate impact on minority and low-income communities in the form of concentrated pollutant emissions from a variety of permitted sources as well as cumulative and synergistic impacts from those emissions. No analysis of environmental justice disparate impacts is being conducted in MDNR's decision to approve, modify, or extend air permits in this environmental justice community, specifically, or environmental justice communities statewide, generally. As recipients of funding from the EPA to operate its Air Pollution Control Program ("APCP"), MDNR is required to comply with the Title VI of the Civil Rights Act of 1964. EPA's Title VI regulations, and Executive Order

Sed(b) (6) Privacy, (b) (7)(C) Personal Privacy (Last visited June 9, 2017).

² See Page 33. Located at: https://www.stlouismo.gov/government/departments/health/ documents/public-health-understanding-our-needs-report.cfm (last visited June 1, 2017).

³ *Id*, at 27.

⁴ Id. at 120-121.

RPC - 13 Project No. 1997-05-009

Great Rivers Environmental Law Center June 12, 2017 Page 3 of 9

12898 which mandate consideration and analysis of environmental justice factors in issuing permits through programs funded by the EPA.⁵

This mandate is clearly not being met, and MDNR depriving environmental justice communities in this area of their civil rights. Without consideration and analysis of environmental justice impacts caused by the pending approval of Mallinckrodt's Part 70 Operating Permit, the administrative process to grant such permit is illegal and in violation of Title VI of the Civil Rights Act of 1964, EPA's regulations promulgated thereunder, and Executive Order 12898. Before issuing a Part 70 Operating Permit to Mallinckrodt, MDNR must conduct a disproportionate impact analysis and conduct air quality modeling for those pollutants capable of causing a disproportionate impact to environmental justice communities located in close proximity to the facility.

These environmental justice issues in North St. Louis City are further exacerbated by the fact that Mallinckrodt has not been issued a Part 70 Operating Pennit twenty years after first submitting an application in March, 1997. Mallinckrodt is one of the largest emitters of air pollution in the City of St. Louis. The facility is located in close proximity to minority and low-income communities. St. Louis is a non-attainment area for particulate matter of 2.5 microns or less (PM_{2.5}). North St. Louis City has the highest levels of PM_{2.5} in the state. Furthermore, North St. Louis City has the highest levels of particulate matter of 10 microns or less (PM₁₀) in the state. Yet, despite Mallinckrodt's twenty-year history of emitting PM_{2.5} and PM₁₀ without a Part 70 Operating Permit in an area that has the worst statewide air quality for these pollutants, a disproportionate impacts analysis has never been conducted for the minority and low-income communities around Mallinckrodt's facility.

Members of these communities report that they are afraid to breathe the air in their neighborhood. They choose not to open the windows in their homes because of strange odors, concerns of pollution, and potential impacts to their health. If the stacks from Mallinckrodt are blowing towards their residences, they often choose to stay inside rather than leaving their

⁵ The Governor's 2017 Recommended Budget states that MDNR's APCP received \$8,272,621 of its \$14,604,059 operating expenses in 2016 from federal funds, including federal grants. See Pages 100-104, located at https://oa.mo.gov/sites/default/files/FY_2017_Natural_Resources_Budget_Request_Gov_Rec.pdf (last visited June 1, 2017).

⁶ Mallinckrodt is the 8th largest emitter of regulated air pollutants based on chargeable emissions according to MDNR records.

⁷ In MDNR's 2016 Air Monitoring Network Plan, on Page 27, MDNR identifies the Blair St. Monitor, located less than 0.5 miles from the Mallinckrodt facility, as having the highest daily and annual values of PM₂₅ (25 ug/m³, 11.0 ug/m³) in the ambient air statewide compared to the National Ambient Air Quality Standards ("NAAQS") for PM₂₅ (35 ug/m³, 12.0 ug/m³).

In MDNR's 2015 Air Monitoring Network Plan, Page 33, the Branch St. monitor, located less than 0.5 miles of the Mallinckrodt facility is identified as having 2.1 exceedances of the PM₁₀ NAAQS and therefore to be in violation of the PM₁₀ NAAQS during the 2012-2014 timeframe. In MDNR's 2016 Air Monitoring Network Plan 2016, Page 33, the Branch St. monitoring is the only monitor in the state that shows an exceedance of the PM₁₀ NAAQS.

Great Rivers Environmental Law Center June 12, 2017 Page 4 of 9

homes. Some have experienced strange phenomenon such as drinking water turning yellow if left outside. They attribute many of these problems to the Mallinekrodt facility. Yet, the facility remains a mystery to them because of a lack of engagement by MDNR or Mallinekrodt in their communities. Of great concern to residents of these communities is the proximity of Mallinekrodt to various schools and daycare facilities, including Ames, Clay, Confluence, Arch Community, and Most Holy Trinity. These disparate impacts to the air quality and health of residents in the area are unacceptable and must be addressed by MDNR and Mallinekrodt going forward.

II. MDNR's Failure to Consider Disparate Impacts to Minority and Low Income Communities Violates Title VI of the Civil Rights Act of 1964, EPA Regulations, and Executive Order 12898.

Recipients of federal funding are prohibited from taking actions that have a discriminatory impact on minority populations. Title VI of the Civil Rights Act of 1964 states:

No person in the United state shall, on the ground of race, color, or national origin, be excluded from participation in, denied the benefits of, or otherwise be subjected to discrimination under any program or activity receiving any federal financial assistance.⁹

EPA's implementing regulations further prohibit recipients of EPA funding from discriminating. Specifically, EPA's Title VI regulations provide that an EPA funding recipient:

... shall not use criteria or methods of administering its program or activity which have the effect of subjecting individuals to discrimination because of their race, color, national origin, or sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program or activity with respect to individuals of a particular race, color, national origin, or sex. 10

In addition to these protections, Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority and Low-Income Populations," provides:

To the greatest extent practicable and permitted by law, ... each Federal agency shall make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States...¹¹

MDNR's decision to approve Mallinekrodt's Part 70 Operating Permit as drafted violates the agency's statutory and regulatory duty to administer all programs and activities in a nondiscriminatory manner. Furthermore, MDNR has failed to satisfy E.O. 12898's requirement

⁹ 42 U.S.C. Section 2000d.

¹⁰ 40 C.F.R. 7.35(b).

¹¹ Exec. Order No. 12898, 59 C.F.R. 7629 (1994).

Great Rivers Environmental Law Center June 12, 2017 Page 5 of 9

that federal agencies identify disproportionate impacts because it has failed to conduct an analysis of the effects of the pollutants emitted by Mallinckrodt on the minority and low-income communities located near the facility. To comply with Title VI, MDNR must conduct air quality modeling and a disproportionate impacts analysis with respect to Mallinckrodt's emissions, but has not done so.

The draft permit documents published by MDNR do not raise or identify the issue of disproportionate impacts at all, much less conduct a disproportionate impacts analysis for PM_{2.5}, PM₁₀. HAPs, VOCs, or the other pollutants emitted by Mallinckrodt on minority and low-income communities around the facility. Without consideration of environmental justice issues. MDNR's actions in approving the draft permit will have an adverse impact that is discriminatory on the bases of race, color, or national origin, and on the basis of economic status. Under the draft permit, residents living near and within the North St. Louis Riverfront Corridor will be exposed to PM_{2.5}, PM₁₀, VOCs, NOx, and HAPs in amounts that are likely to threaten human health. Residents in this area are disproportionately African American and low-income compared to other areas of St. Louis. Therefore, MDNR's decision to approve Mallinckrodt's Part 70 Operating Permit as drafted will disparately impact minority and low-income communities in violation of Title VI.

Even if the issuance of Mallinckrodt's permit complies with the National Ambient Air Quality Standards ("NAAQS") for various criteria pollutants and National Emissions Standards for Hazardous Air Pollutants ("NESHAPs") for hazardous air pollutants, such compliance does not absolve MDNR and Mallinckrodt from performing a disproportionate impact analysis related to the issuance of the permit on neighboring communities. Since 2013, EPA's Office of Civil Rights ("OCR") has stated in guidance documents that it "will no longer presume an absence of adversity if a NAAQS (or other health-based threshold) is satisfied." EPA explained that "presuming compliance with civil rights laws wherever there is compliance with environmental health-based thresholds may not give sufficient consideration to other factors that could also adversely impact human health." Is

Therefore, relying on the NAAQS and NESHAP in the absence of a disproportionate impact analysis is not sufficient to ensure compliance with Title VI requirements under OCR policy because low income communities are considered to be at particularly high risk for exhibiting health impacts from exposure to various pollutants. and because the neighborhoods along the North St. Louis Riverfront Corridor are already struggling with the cumulative effects of multiple sources of pollution. OCR's position has been applied to Title VI complaints filed with EPA, in which OCR explained "compliance with federal and/or state environmental"

¹² Environmental Protection Agency, Title VI of the Civil Rights Act of 1964: Adversity and Compliance with Environmental and Health-Based Thresholds 4. January 24, 2013.

¹⁴ See , e.g., National Ambient Air Quality Standards for Particulate Matter, 78 Fed. Reg. 3086 (Jan. 15, 2013) ((codified at 40 C.F.R Parts 50, 51, 52, 53, and 58) ("2013 Final Rule") at 3104.

Great Rivers Environmental Law Center June 12, 2017 Page 6 of 9

regulations, does not, by itself, ensure compliance with Title VI."¹³ Similarly the EPA Environmental Appeals Board has held that technical compliance with NAAQS is inadequate for compliance with Executive Order 12898.¹⁶

To remedy violations of Title VI, EPA regulations, and Executive Order 12898, MDNR should require Mallinekrodt to conduct a robust analysis of disproportionate impacts to North St. Louis City communities, including cumulative impacts from other nearby permitted facilities regulated by MDNR under the CAA, and allow public comment on that disproportionate impacts analysis. Alternatively, MDNR should conduct such analysis itself for public comment.

III. MDNR's Failure to Provide a Grievance Procedure for Environmental Justice Complaints to Minority and Low Income Communities Violates EPA Regulations Promulgated Under Title VI of the Civil Rights Act of 1964

MDNR lacks a grievance procedure for environmental justice complaints as required by law. EPA's Title VI implementing regulations state that each recipient of EPA funding shall "adopt grievance procedures that assure the prompt and fair resolution of complaints which allege violation of this part." MDNR has adopted no such procedures and is therefore in violation of this regulation. To remedy this violation of EPA regulations, MDNR should develop a complaint procedure whereby members of minority and low-income communities are provided a vehicle to address potential environmental justice and civil rights issues in MDNR's air permitting process. Such grievance process could be modeled after EPA's Office of Civil Rights complaint process or other states that have adopted similar processes such as Illinois. 18

Furthermore, MDNR needs to put forth more effort in engaging minority and low-income communities that are impacted by air pollution, such as the neighborhoods impacted by Mallinekrodt's facility. The issuance of a public notice is not sufficient to meet this need because minority and low-income communities are the least likely groups to be able to effectively navigate and comment on public notices for draft permits. To this end, MDNR should create a position within the APCP for an Environmental Justice liaison to engage and inform minority and low-income communities when air permitting and siting decisions are proposed that might have disproportionate impacts on such communities. MDNR should proactively facilitate informational meetings for minority and low-income communities when air permitting decisions are proposed that might impact such communities. Without these types of components, MDNR's APCP remains in violation of Title VI regulations.

¹⁷ 40 C.F.R 7.90(a).

¹⁵ See Angelita C. et al v. California Department of Pesticide Regulation, US EPA, Re: Title VI Complaint 16R-99-R9 (2011).

¹⁶ See In ra Shall Gulf of Mexico Inc., No. 1550, 2010 WL 9564110 (EAB 2010).

¹⁸ http://www.epa.illinois.gov/topics/environmental-justice/ej-policy/index.

Great Rivers Environmental Law Center June 12, 2017 Page 7 of 9

The commenters note that around the time when Mallinckrodt first submitted an application for a Part 70 permit in 1997, the company held informational meetings for the neighboring communities to discuss concerns regarding air pollution from the facility. Community members found them valuable in understanding Mallinckrodt's operations and to have their concerns addressed. MDNR or Mallinckrodt should reinstitute these meetings as a means to address concerns regarding air pollution in the area and to disseminate information to the public about air pollution and the regulatory process of air permitting.

IV. MDNR Should Further Limit Emissions of Several Air Pollutants

Several Emission Limits presented in Section III of the Draft Permit should be lowered because they will not be protective of ambient air quality and human health:

NOx: The limit in the draft permit for NOx is 39 tons per year (tpy) for all permitted features. Mallinckrodt's Emission Inventory Questionnaires ("EIQs") from 2008-2016 demonstrate a downward trend of NOx emissions from 107.1 tpy in 2008 to 29.30 tpy in 2016. Allowing Mallinckrodt to suddenly reverse trend and emit 10 tpy more in 2017 than in 2016 would constitute a significant increase of NOx into the ambient air in an area that is already designated as non-attainment for ozone and PM25. Since NOx is a precursor for ozone, allowing Mallinckrodt to emit 10 tpy will further contribute to ambient air quality exceedances and violations of the ozone NAAQS. Furthermore, NOx is a precursor to PM2.5. As stated above, the area around the facility is already in non-attainment for PM2.5 and experiences the highest levels of PM2.5 in the ambient air statewide. Allowing an additional 10 tpy of NOx per year will further degrade the ambient air in North St. Louis City. A review of a prior draft permit from 2013 suggests that 24.45 tpy would be an appropriate limit in Mallinckrodt's permit and that the 39 tpy limit in the draft permit was arbitrarily selected without justification for the convenience of the permittee. Selecting the 24.45 tpy emission limit for NOx would continue the downward trend and would help to meet ozone and PM25 NAAQS in the region and help to improve ambient air quality in North St. Louis City.

VOCs: The Total VOC emission limit of 211.82 tpy is more than five times higher than Mallinekrodt's VOC emissions reported in its 2016 EIQ of 38.10 tpy. The most VOCs Mallinekrodt has emitted since 2008 is 43.8 tpy. Setting the emission limit at 211.82 tpy would allow Mallinekrodt to emit VOCs in a quantity that would negatively impact human health and ambient air quality. Furthermore, because VOC is a precursor to ozone, allowing a five-fold increase in VOC emissions from one source would likely contribute to further exceedances of the ozone NAAQS in an area of non-attainment for ozone.

Total HAPs: The Total HAP limit of 143.43 tpy is significantly higher than Mallinckrodt's reported HAPs from 2012-2016, which ranged from 1.18 tpy to 3.12 tpy. It is unclear from the Statement of Basis or other documents in Great Rivers' possession why there is such a vast discrepancy between reported HAPs and proposed HAP emission limits. We note that in earlier years, Mallinckrodt and/or MDNR were combining VOC and PM10 with HAPs in EIQs. However, these values still do not explain the vast discrepancy described above. MDNR's allowance of 143.43 tpy or 286,860 lbs per year for the next five years to Mallinckrodt

Great Rivers Environmental Law Center June 12, 2017 Page 8 of 9

to emit air pollutants deemed hazardous for being suspected of causing cancer or other serious health effects, such as reproductive effects or birth defects, will have a disproportionate impact on minority and low-income communities near the facility.

V. General Typographical errors

We provide the following non-substantive suggested corrections to the draft permit for accuracy:

Page 8

Monitoring:

1. The permittee shall conduct visible emissions observations on each emission unit using the procedures contained in USEPA Test Method 22. The permittee is only required to make observations when the emission unit is operating and when the weather conditions allow. If the permittee observes no visible emissions, then no further observations are required.

Page 19

k. In all cases where the provisions of this subpart require a permittee to repair leaks by a specified time after the leak is detected, it is a violation of this section to fail to take action to repair the leaks within the specified time. If action is taken to repair the leaks within the specified time, failure of that action to successfully repair the leak is not a violation of this section. However, if the repairs are unsuccessful, and a leak is detected, and the permittee shall take further action as required by applicable provisions of this section. [§63.1255(a)(12)]

Page 26

iv. Records. In addition to records required by §63.1255(g), the permittee shall maintain records specified in §63.1255(e)(5)(iv)(A) through (D). [§63.1255(e)(5)(iv)]

Page 35

ii. For equipment complying with the provisions of §63.1255(b) through (g), except §63.1255(b)(4)(iv) and §63.179, the summary information listed in §63.1255(h)(3)(ii)(A) through (L) for each monitoring period during the 6-month period. [§63.1255(h)(3)(ii)]

Page 62

3. The permittee shall operate, monitor, and perform recordkeeping on this equipment in as required in 40 CFR part 63 Subpart GGG.

Great Rivers Environmental Law Center June 12, 2017 Page 9 of 9

Page 79

1) The permittee shall submit a Full Emissions Report either electronically via MoEIS, which requires Form 1.0 signed by an authorized company representative, or on Emission Inventory Questionnaire (EIQ) paper forms on the frequency specified in this rule and in accordance with the requirements outlined in this rule. Alternate methods of reporting the emissions, such as a spreadsheet file, can be submitted for approval by the director.

Page 126

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Statement of Basis

SB-1

The Statement of Basis for the permit states that MDNR relied on Mallinckrodt's "2015 Emissions Inventory Questionnaire, received April 29, 2016" as a reference in drafting the Part 70 Operating Permit. This should be changed to "2016 Emissions Inventory Questionnaire, received April 29, 2017" as the 2016 EIQ numbers are referenced in Table SB 1.

We appreciate the opportunity to comment on the draft permit on behalf of the other concerned entities of North St. Louis City and hope that MDNR will take the concerns addressed in this comment letter seriously, and we look forward to MDNR's response.

Sincerely.

Bob Menees Staff Attorney